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APPLICATION NO.

FILING DATE

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CONFIRMATION NO.

09/737,908

12/15/2000

Jason Hill

CUB-5

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CUBIST PHARMACEUTICALS, INC.

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LEXINGTON, MA 02421

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/737,908

Applicant(s)

HILL ET AL

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-31 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 3, 5, 6 and 10-16 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 11/28/05, claims 3, 8, 31 have been amended. Claims 3-31 remain pending.

Claims 3-17 are examined in this Office action; claims 18-31 remain withdrawn from consideration. Claim 4 is characterized as allowable; claims 3, 5, 6, 10-16 are now rejected, and claims 7-9 and 17 are objected to because of their dependence on rejected claims.



Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 11/121851. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the respective genera. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].



Claims 13-16 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is recited to be dependent on claim 4 (or else claim 3). Claim 4 requires B' and A' to be joined together to form a heterocyclic ring. As it happens, only one of the compounds (compound # 189) recited in claim 13 is subgeneric to claim 4. Similarly, none of the

compounds in claims 14-15 are subgeneric to claim 4. One option would be to put compound #189 into a separate claim.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 5, 6, 10-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Abbot (USP 4,537,717).

As indicated previously, Abbot discloses compound 23 in table III. This compound is encompassed by claim 3 when the substituent variables are as follows:

$R = N(B)(X)_m-A$, wherein

B = hydrogen

X = -CO-

A = alkyl

$R^1 = -N(B')(X')_m-A'$, wherein

B' = hydrogen

m = 0

X' = not present
A' = C12-alkyl which is substituted with oxo.

R² = -CH₂-CO- aminophenyl

Thus, the claims are anticipated on this basis. There is, moreover, another compound disclosed by the reference which is also encompassed by instant claim 3. Consider the structure at col 5, line 40+ of the reference. Variable R^o (of the patent) can be an amino protecting group such as *tert*-butyloxycarbonyl. If there were no provisos in instant claim 3, this compound would be encompassed when B' is hydrogen, X' is carbonyl, and A' is alkoxy. The situation is complicated by the fact that claim 3 includes a proviso (page 4 of 69) that when B' is hydrogen and X' is carbonyl, then X'-A cannot be a carbamate protecting group. However, this proviso is not effective to overcome the rejection based on the disclosure of this compound. The reason is that it is not meaningful to recite that a given subgenus is excluded when X' is carbonyl if "m" is not specified. Thus, the compound in question is encompassed by instant claim 3 when the variables (which make up R¹) are as follows:

B' = hydrogen
m = 0
X' = >C=S
A' = *tert*-butoxy carbonyl (i.e., "carboalkoxy").

In the foregoing, X' has been arbitrarily assigned the substituent thiocarbonyl. But the reference would be equally valid for the case of X' being S=O or SO₂; since "m" is zero, the proviso is circumvented for any value of X' other than carbonyl itself (and is possibly circumvented even for the case of X' representing carbonyl).

The rejection is maintained.

✦

It is suggested (but not yet required) that applicants amend claim 31 to recite process steps. This will help to advance the prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
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